

Application No.: 10/067,620  
Amendment Under 37 CFR 1.111

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Docket No.: 416272003400

### REMARKS

Reconsideration is respectfully requested. Claims 1-16 were previously pending in the application. Claims 4-7 and 13-16 have been cancelled without prejudice to filing these claims or similar claims in one or more divisional or continuation applications. Claims 1-3 and 8-12 have been amended. The amendments merely recast the compositions claims as method claims. Thus, no new matter has been added. Amendment and cancellation of claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Accordingly, claims 1-3 and 8-12 are now pending.

#### Restriction Requirement

Applicants acknowledge the Examiner's decision to make the Restriction Requirement final. Applicants had previously elected with traverse Group I, claims 1-3 and 8-12. Accordingly, Applicants have cancelled claims 4-7 and 13-16 by this amendment. Applicants expressly reserve the right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application or an application claiming priority from this application.

#### Claim rejections under 35 U.S.C. § 102(a) and (b) based on the Del Val reference

The examiner has rejected claims 1-4, 14-18, and 22-24 under 35 U.S.C. § 102(a) or (b) as allegedly being anticipated by Del Val et al. (reference 6 on the IDS submitted 2/3/03). Applicants respectfully traverse the rejection of these claims under the different sections of 35 U.S.C. § 102 as discussed below.

The claims have been amended to recast the claims from diagnostic and therapeutic compositions for ryegrass or walnut pollen allergy to the corresponding methods. Since Del Val et al. do not teach any relationship between the Ambt 7 protein from ragweed pollen and ryegrass or walnut pollen allergenic proteins, Del Val et al. fails to anticipate the present claims. Further, given the lack of any teaching of such a relationship, one of skill in the art would not be in any way

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motivated to modify the teachings of Del Val et al. to the methods of the presently claimed invention, so Del Val et al fail to render the present claims obvious..

Claim rejections under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1-3 and 8-12 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges that "[t]he scope of claims 1 or 8 reads upon *any* protein or polypeptide that comprises SEQ ID NOs 1-11". (Emphasis added.) Office Action at page 3, paragraph listed as 5. For this reasons, the Examiner alleges that there is inadequate "written description of a genus of thousands or even possibly millions of proteins or polypeptides encompassed by claims 1 or 8." Applicant respectfully traverses this rejection as explained below for each group of rejected claims.

With respect to the rejection of claim 1, this claim has been amended to recite "said protein is selected from the group consisting of a ryegrass pollen allergen, a walnut pollen allergen, and a ragweed pollen allergen each of which comprises an amino acid sequence selected from the group consisting of SEQ ID NO:1 . . . , and SEQ ID NO.11." Applicants respectfully submit that the scope of claim 1, as amended, is not unduly broad and does not read upon *any* protein or polypeptide that comprises any of the listed sequences. Rather, the scope of the claim covers "a ryegrass pollen allergen, a walnut pollen allergen, and a ragweed pollen allergen" that comprises any of the listed sequences. As to the claimed protein, Applicants respectfully submit that the specification provides ample written description of "an isolated ragweed protein". For instance, the specification provides structural and chemical information on the claimed ragweed protein. In paragraph 175 of the specification, the isolated ragweed protein is described as being a 30 kDa glycoprotein which has at least one disulfide bond and a pI of about 8.0. Furthermore, it is disclosed in paragraphs 184-195 of the specification that the ragweed protein as isolated by the methods disclosed in the application yields peptides corresponding to the sequences of SEQ ID NO:1-11 when subjected to tryptic digestion. The sequence information, combined with the physical characteristics of the protein, provides structural information which uniquely describes the

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claimed ragweed protein. In addition, the specification in paragraph 180 demonstrates that sera from patients allergic to ryegrass and to walnut shows cross reactivity to the ragweed protein thus demonstrating the utility of the ragweed protein in diagnostic and therapeutic applications for patients allergic to ryegrass and walnut. In addition, this clearly demonstrates that both ryegrass and walnut contain closely related proteins that are within the written description given the cross reactivity of the antibodies.

With respect to the rejection of claim 8, as discussed above, the specification provides clear support for the three proteins covered by the claim. Furthermore, the specification provides an example of generating fragments from the three proteins by tryptic digests. Thus, one of skill in the art would recognize upon review of the specification that the inventors had possession of the presently claimed inventions in both claims 1 and 8 as well as the claims that depend therefrom.

For the foregoing reasons, Applicants have overcome the Examiner's written description rejections. Applicants thus respectfully request that these grounds for rejection be withdrawn.

Claim rejections under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1-3 and 8-12 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges that "[t]he scope of claims 1 or 8 reads upon *any* protein or polypeptide that comprises SEQ ID NOs 1-11". (Emphasis added.) Office Action at page 3, paragraph listed as 5. For this reasons, the Examiner alleges that there is inadequate "written description of a genus of thousands or even possibly millions of proteins or polypeptides encompassed by claims 1 or 8." Applicant respectfully traverses this rejection as explained below for each group of rejected claims.

Double patenting rejection

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The Examiner has rejected claims 1-3 and 8-12 provisionally under 35 U.S.C. § 101 as allegedly claiming the same invention as that of claims 3-4 and 22-24 of copending Application No. 10/067,484.

Applicants respectfully disagree with the Examiner's grounds for rejection and the above statements. However, in order to facilitate prosecution in this case applicants have amended the pending claims, without prejudice or disclaimer, to recite diagnostic and therapeutic methods of using the compositions rather than the compositions. Therefore, applicants respectfully request that the Examiner withdraw the provisional double patenting rejection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 416272003400. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: June 10, 2005

Respectfully submitted,

By [Signature]

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